IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

J.B.D.L. Corp. d/b/a BECKETT APOTHECARY, et al.,	)	Civil Action No. C-1-01-704
Plaintiffs,	)	Judge Sandra S. Beckwith
	)	Magistrate Judge Timothy S. Hogan
v.	)	
WYETH-AYERST LABORATORIES, INC., et al.,	)	
Defendants.	)	
CVS MERIDIAN, INC. AND RITE AID CORP.,	)	
Plaintiffs.	)	
v.	)	Civil Action No. C-1-03-781
WYETH,	)	Judge Sandra S. Beckwith
	)	Magistrate Judge Timothy S. Hogan
Defendant.	)	

REBUTTAL EXPERT REPORT OF P.O. SIMON, R.Ph.

I. Qualifications and Assignment

I am an expert in the field of pharmaceutical marketing and sales and make this statement as an independent consultant.

My experience relating to pharmaceutical marketing and healthcare economics spans over twenty-five years in diverse healthcare and business settings. See my Curriculum Vitae (Exhibit "A"). My early career included sales representative experience and management of marketing research and information planning at two large pharmaceutical companies - Hoffmann-La Roche and Bristol-Myers Squibb Company. I directed all marketing activities and led the managed care sales force while at Teva Pharmaceuticals, a leading manufacturer of

generic pharmaceuticals. At Medi-Span, the leading provider of automated clinical record systems, and at Taro Pharmaceuticals, I built marketing departments with responsibility for developing marketing strategies and launching new products. At Sigma-Tau Pharmaceuticals I was responsible for Marketing, Sales, Distribution and Customer Service. I also built a National Accounts department.

I have consulted for the following companies on a wide range of topics, including pharmaceutical marketing plans and strategies:

- Odyssey Pharmaceuticals
- Pharmacia Corporation
- Sidmak Pharmaceuticals
- Medirex Pharmaceuticals
- PoliChem Pharmaceuticals (European)
- Forrest Laboratories
- Astra/Zeneca
- Ruane, Cunniff & Company, Inc. (Investment Banking)
- Susman Godfrey, LLP
- Clinical Advisors
- Hoffmann-LaRoche
- Johnson & Johnson
- McAccess (Managed Care contract sales)

I have consulted as an expert in one other case in the past (Duramed). I am being compensated at the rate of $350/hour for my time preparing this report and for testifying.

II. Summary

I am responding to certain statements and opinions relating primarily to pharmaceutical marketing issues in the reports of Dr. E.M. Kolassa and, where I have knowledge, to the expert reports provided by Kimberly P. McDonough and Kenneth W. Schafermeyer. In this report, I focus my attention primarily on Dr. Kolassa.

Contrary to these defense experts, in my opinion:

1. Cenestin had sufficient indications, dosage strengths and characteristics that gave

it value in the market at the time of typical formulary review.

2. Duramed's marketing efforts for Cenestin were appropriate and not deficient.

3. Despite Duramed's competitive efforts, Cenestin's access to managed care lives was not on the "same basis as Premarin" in "60% - 75%" of the lives as Dr. Kolassa maintains (Kolassa Report at 21). Cenestin was at a substantial disadvantage because of Wyeth's exclusionary contracts with managed care organizations (MCOs) and pharmacy benefit managers (PBMs).

4. Contrary to what Dr. Kolassa maintains, the exclusionary rebate agreements covering the Premarin Family were not standard in the industry.

5. Contrary to the statements of Kolassa, McDonough and Schafermeyer, the fact that a formulary is designated as "open" does not equate to equal access or reimbursement.

6. The evidence shows there was sufficient market interest in Cenestin from physicians and consumers for Cenestin to have gained significant market share in the absence of Wyeth's exclusionary contracting strategies challenged in this case.

The materials I have relied upon in writing this report are listed in Exhibit "B".

III. Cenestin is a pharmaceutical product with a value in the market.

A. Cenestin compares favorably to Premarin.

Cenestin is not substandard as Dr. Kolassa implies. In fact, Cenestin's pharmacokinetic profile and improved dosage uniformity[1] compare favorably to Premarin. In addition, Cenestin's non-animal source provided an advantage with a segment of the patient population. Cenestin was

[1] The pharmacokinetic profile of a drug refers to the absorption, distribution, metabolism and excretion of the product in the body. Dosage uniformity is a measure of sameness defined by the United States Pharmacopeia (USP). It is a standard test of how well a batch of tablets compares with the labeled amount of active ingredients. Cenestin has advantages over Premarin in these and other areas. Sarrel II Report at 6-15.

initially priced at a small discount to Premarin to create an image appropriate in the marketplace.

I disagree with Dr. Kolassa regarding Cenestin's initial pricing. In my opinion, Duramed followed a prudent pricing strategy. One analogous situation that demonstrates my point involves amoxicillin. There, amoxicillion had a favorable pharmacokinetic profile. It was launched at price parity or above and very rapidly took over the market from ampicillin. Even though both products (ampicillin & amoxicillin) have the same indications, side-effects, and the same antibiotic spectrum, amoxicillin had a favorable pharmacokinetic profile and took over the market with a higher price than ampicillin, which was the standard treatment for many respiratory tract infections at the time.

B. Cenestin was offered in the necessary strengths.

Manufacturers do not want to delay introduction of their products to physicians once they are approved by the FDA. While the 1.25 mg dosage of Cenestin was not approved in March 1999 when the 0.625 mg and 0.9 mg dosages were approved, it was introduced within approximately eight months of the product launch. The 0.625, 0.9 and 1.25 mg dosages accounted for over 90% of Premarin tablet sales.[2] The lack of dosage strengths taken by one-tenth of Premarin users did not significantly impact Cenestin's sales.

C. Class effect.

The FDA approved Cenestin as synthetic conjugated estrogens A. As such, pharmacists and physicians expect Cenestin and Premarin to work in a similar if not identical set of indications and uses. Wyeth saw another conjugated estrogen as a potential problem and predicted a market share increase for Cenestin of 5% due purely to Cenestin being termed a conjugated estrogen. WYE 51510. Indeed, one of the key concerns motivating the Premarin Preemptive Plan was Wyeth's

[2] IMS NPA extended units data for the first half of 1999 cited in Kolassa I Report at 26. He also notes there that Cenestin's .3mg dosage was approved in June, 2002.

expectation of Cenestin, a conjugated estrogen drug, coming to market. WYE 132250-132311. Wyeth developed managed care strategies based on the rebate leverage it felt it would need to use to keep Premarin business in MCOs and PBMs. See, e.g., WYE 117994-118056. Wyeth also conducted a survey of retail pharmacists to better understand how they would interpret the similar names. About half of the retail pharmacists surveyed responded that there was the potential for unintentional interchange between Premarin and Cenestin based on the common conjugated estrogen classification. WYE 051569. When asked if they would therapeutically switch Premarin prescriptions to Cenestin upon patient request, 83 percent responded they would. WYE 051572.

Furthermore, when looking at the patient materials provided to PBMs, MCOs and pharmacies by drug reference companies (like Medi-Span and First DataBank which specialize in providing pharmaceutical data) for both Premarin, and Cenestin, they appear identical, and include mention of the osteoporosis indication. A current example of educational materials provided to patients getting Cenestin is from Medco's website:

Brand Name	Drug Class	Generic Available?
CENESTIN	Sex hormones, estrogens	No

Active Ingredient:
Synthetic conjugated estrogens
Type of Drug:
Female hormones
Uses:
To treat hot flashes associated with menopause.

To prevent osteoporosis (brittle bones) related to a lack of estrogen after menopause.

To treat vulval, vaginal, and lower urinary tract tissue breakdown, drying, and thinning following menopause. Estrogen supplements may prevent or decrease complications and symptoms such as dryness, itching, and burning in and around the vagina, and urinary tract infections.

For estrogen replacement therapy after failure of the ovaries due to menopause, disease, or surgical removal.

To treat advanced androgen-dependent cancer of the prostate gland in men.

To relieve the symptoms of breast cancer in selected men and women, or those with metastatic disease.

To treat vaginal atrophy and kraurosis vulvae, a condition involving the breakdown and drying of the external female genitals.

In July 2002, the WHI study tarnished the image of HRT products and made the osteoporosis and long term use indications for ERT products as well much less attractive to physicians and consumers. This, coupled with dosage/strength parity between Premarin and Cenestin, removed the perceived product deficiencies asserted by Dr. Kolassa. Also, Cenestin's later price advantage should have made it attractive to MCOs but it failed to gain market share primarily because it continued to have difficulty gaining favorable status on formularies. See, e.g., Gibson Report II at 61 and AHP 339061.

D. Lack of demand was not the issue.

Kolassa, Schafermeyer and McDonough point to financial considerations as being secondary to clinical aspects and physician/consumer demand when it comes to formulary position. Kolassa goes on to say "[w]hen there are multiple drugs with similar clinical profiles, however, the attractiveness of the products from a cost standpoint may be examined." Kolassa Report at 10. This is the case with Cenestin. There was no way that Duramed could provide the financial incentives needed to fight Wyeth rebates. While Kolassa presents a financial analysis of the impact of a 7% share change and the required elements that Duramed would need to provide, he does not address the total rebate package of Wyeth (Premarin and other Wyeth branded products, either bundled or incentivized) which would be impossible for Duramed to match. He states that "the potential loss of rebates on other Wyeth products could have easily been offset through rebates on competitive

products from other manufacturers." Kolassa Report at 21. I have never heard of a successful negotiation like this being done by a manufacturer for another company's products. Duramed simply could not tell a MCO or PBM to go to another pharmaceutical company to replace a lost Wyeth bundled product.

Kolassa, as well as McDonough & Schafermeyer, maintain that MCOs and PBMs respond to demand from physicians and consumers with respect to formulary decisions. This may apply to products with no competitive alternatives but not to competitors like Cenestin and Premarin with similar uses and conjugated estrogen names. In such cases, Pharmacy and Therapeutic (P&T) committees typically return their recommendation for a decision to be made by others based on financial considerations. See, e.g., Hill Dep I at 100-102.

IV. Cenestin did not have equal access to 60-75% of managed care lives.

A. Industry figures do not agree with Dr. Kolassa's position.

Dr. Kolassa asserts that Cenestin had access to 60-75% of managed care lives on the same basis as Premarin. Kolassa Report at 21. This figure is incorrect and greatly over-estimates the number of lives to which Cenestin had access on the same payment and authorization terms as Premarin.

The 2001 Pharmacy Benefit Report published by Novartis is widely regarded as the most accurate assessment of the HMO pharmacy benefit publicly available. In 2000, over 79 million lives were enrolled in HMOs (Novartis PBR report at 2), representing about one-third of the U.S. population with health benefits. Table I shows that in 2000, only 18.9% of HMO lives were enrolled in plans where all branded products had the same co-payment. This figure is obtained by adding the "Open" column for One Tier and Two Tier co-payment designs. All other cells represent benefit types where products would either require higher patient co-pays than preferred products or not be

reimbursed at all. This is very close to the Wyeth reported statistics where open formulary (one & two tier) plans cover 22% of HMO lives. WYE 089414.

Table I

2000 HMO Drug Benefit Enrollment by Copayment Design, Formulary Type, and Lines of Business

	Formulary Type											
	Commercial Group			Medicaid			Medicare			Overall		
Copayment design	Open	Selective/ Partially Closed	Closed	Open	Selective/ Partially Closed	Closed	Open	Selective/ Partially Closed	Closed	Open	Selective/ Partially Closed	Closed
One Tier	7.1%	1.3%	7.2%	38.0%	27.1%	27.1%	4.8%	0.0%	0.2%	9.7%	3.5%	8.4%
Two Tier	10.8%	4.0%	16.0%	0.0%	0.0%	0.3%	5.4%	8.7%	17.8%	9.2%	4.1%	14.7%
Formulary/ Non-formulary	1.5%	3.2%	0.0%	0.0%	0.0%	5.1%	0.0%	5.3%	0.0%	1.2%	3.1%	0.5%
Preferred/ Non-preferred	0.6%	0.0%	0.2%	0.0%	0.0%	0.0%	0.0%	0.0%	0.6%	0.5%	0.0%	0.2%
Three Tier	36.4%	8.0%	3.8%	1.0%	0.0%	1.4%	36.0%	8.8%	3.9%	33.0%	7.3%	3.6%
Four Tier	0.1%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	0.0%	8.5%	0.1%	0.0%	0.8%
Total	56.4%	16.5%	27.1%	39.0%	27.1%	33.9%	46.1%	22.8%	31.0%	53.8%	18.1%	28.1%
LOB Total	100%			100%			100%			100%		

Pharmacy Benefit Report: Facts & Figures, 2001 Edition

B. Internal company documents fail to support Dr. Kolassa's position.

While Dr. Kolassa's report states that Cenestin had access to about two-thirds of managed care lives, Wyeth and Duramed documents show figures that more closely correspond to the Novartis pharmacy benefit report and my own understanding of formularies in the period 1999-2000. These documents report that Cenestin was reimbursed for only about one-third of over 200 million managed care lives and had restrictions on its reimbursement in two-thirds. See, e.g., VIK 116-118.

C. Wyeth personnel reported that Duramed's access to managed care was restricted by Wyeth's contracts.

Dr. Kolassa's assertion, that 60-75% access for Cenestin in open formularies means that Premarin and Cenestin are treated equally by MCOs and PBMs is not correct. Wyeth's own employees report in Wyeth internal memos that Wyeth's contracts restricted access to Cenestin in large managed care accounts[3]. Statements that Cenestin's access to managed care was not restricted are not credible.

D. Restriction in 25%-40% of the market is sufficient to seriously affect Cenestin's sales.

Even if Cenestin is explicitly excluded from 25%-40% of managed care lives,[4] this figure is still sufficiently restrictive to result in decreased Cenestin prescribing by physicians.[5]

For a drug to be disadvantaged by a third of the doctor's managed care patient load is a significant disadvantage for the drug. The disadvantage is obvious. Assume a doctor has written ten prescriptions for a drug (Cenestin) that is not approved by three of those ten patients' health plans. That translates into three pharmacy calls. The office nurses must pull the chart and the doctor has to review it during, or at the end of, office hours. Now the pharmacy must be called to permit the substitution with an approved formulary drug. The office must then update and re-file the patient records. Meanwhile the patient eventually gets her prescription filled with Premarin

[3] The documents to which I refer include WYE 23598 and WYE 117064.

[4] By citing Dr. Kolassa's figures I do not accept them as an accurate portrayal of the true level of restriction which I believe to be higher.

[5] While I was the Director of Market Planning at Medi-Span, I investigated the development of a computerized formulary software package to be used by physicians. This project required me to research the impact of formularies on physician prescribing. During the project, I spoke with many physicians about the prescribing process and found that non-formulary drugs face significant roadblocks in a physician's practice.

or another formulary drug. The next time she talks to her doctor she may express her dissatisfaction that he/she prescribed a drug she could not get under her health plan.

E. Spillover[6] exists and pharmaceutical manufacturers take advantage of it.

My experience with managed care formularies and in physician discussions while at Medi-Span is that spillover exists and that it is a powerful market force. When talking to physicians about providing formularies in their practice management software they explained to me the difficulties that they encountered when serving patients from multiple managed care situations. A typical doctor's description would be:

> I have patients from several (some claimed as many as 12) managed care organizations coming to me for treatment. I find it impossible to keep track of all the formularies and I look for one product that is approved on virtually all formularies. Even with the representatives providing books that define the formularies for these managed care organizations, I just find it too much of a hassle to keep track of an individual's coverage.

Dr. Kolassa attempts to minimize the importance of spillover by arguing that the spillover effect has never been measured empirically. However, he admits that examples exist (HMSA formulary-Kolassa II dep at 173) that demonstrate the impact a formulary can have on patients other than those covered by the formulary. My own experience with physician interviews is that they tend to use the products that generate the least calls from pharmacists and patients. Physicians are looking for products that will meet their clinical needs while also minimizing interruptions. This is becoming even more common today as managed care exerts even more

[6] Spillover is the impact (or result) of influence exerted on one group by the actions (or decision) of another. In the context of physician prescribing it simply means that if patient group one can use any product but patient group two can only use product ABC then it is easier to use ABC for both groups one and two. As such, physician prescribing behavior for group two has influenced (Spilled Over) the physician prescribing behavior on group one.

pressure and influence in the healthcare market. The fact that Cenestin has similar market shares[7] relative to Premarin across payor segments is testament to the fact that doctors will use the same products for their cash paying patients as they use for their formulary patients. Doctors do not use different products for different classes of patients. Spillover is real and powerful.

F. Retail prices are not insignificant compared to MCO co-payments.

Kolassa, McDonough and Schafermeyer go to great lengths to say that the difference between the usual and customary (U&C) (See, e.g., McDonough Report at 20) price and Tier 2 co-pays are insignificant. Nothing can be further from reality. They present the case of the 0.625mg tablet for 30 days but totally disregard the 1.25mg strength and mail order, which provides 90 days therapy at about twice the retail co-pay. Table II provides the U&C prices that were obtained from chain stores in the IMS - National Presciption Audit. As demonstrated below, the U&C (cash) prices are not calculated the same way that reimbursements by PBMs and MCOs to pharmacies are calculated. While retail pharmacies typically bill PBMs and MCOs on a formula lower than manufacturer list prices (AWP - 12% plus dispensing fee of $2.00) (see e.g., McDonough Report at 20 and DUR 006269 - I used the more conservative figure), cash prices are not calculated the same way and the difference between U&C and the reimbursement prices are significant. As an example, the average U&C price for Cenestin 0.625mg during the first half 2002 is $22.24 and a prescription for 1.25mg tablets is $29.88. The calculation used by Wyeth

[7] Carlton II Report, Tables 3-6.

experts predicts a cash price of $19.89 for the 0.625mg tablet and $26.94 for the 1.25 mg tablet (extrapolated from McDonough Report at 20).[8]

Table II

Average Retail Price TRx (30 day supply)

		2H1999	1H2000	2H2000	1H2001	2H2001	1H2002	2H2002	1H2003	2H2003
PREMARIN										
	1.25MG	22.88	24.50	26.00	28.46	30.17	32.08	34.41	38.97	40.01
	0.9MG	21.05	22.45	23.77	25.33	26.43	28.30	30.28	34.31	35.49
	0.625G	16.92	18.16	19.32	20.71	21.60	23.08	24.90	28.17	29.44
CENESTIN										
	1.25MG	_____	21.08	21.76	27.48	27.72	29.88	32.06	36.37	37.47
	0.9MG	17.31	21.52	21.45	24.43	24.24	26.50	28.25	31.78	33.62
	0.625G	16.25	16.75	17.27	20.07	20.53	22.24	23.65	26.80	27.97

Source: IMS Monthly NPA (Chain Store retail data)

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[8]

Weighted Annual AWP's*

Product	Strength	Size	1999	2000	2001	2002
Cenestin	0.625	100	52.02	52.78	62.04	70.71
	1.25	100	n/a	64.64	86.48	98.54

*AWP's reported by Medi-Span weighted for months in effect.

Cenestin Prices

	0.625mg	1.25mg
AWP/30 tabs*	20.33	28.34
PBM (AWP - 12% + $2.00)	19.89	26.94
Patient U&C**	22.24	29.88

* weighted average 1H2002
** Table II U&C from 1H2002

The retail average co-payment amounts from the Takeda Report (McDonough 000065) can now be compared to the audited U&C prices. As demonstrated by Table III below, the prices a patient would be required to pay versus the typical tier 2 co-pay are considerably higher than the $0.57 (McDonough Report at 20) predicted by McDonough. The U&C monthly Cenestin cash price differences from 2d tier co-pays constituted a substantial roadblock to the use of Cenestin.

Table III

Cenestin Retail price difference from 2nd Tier Co-Pay
30 day supply*

		1999	2000	2001	2002
2nd Tier Co-Pays		**12.82**	**14.14**	**16.06**	**17.57**
1 month	0.625	3.43	2.87	4.24	5.38
1 month	1.25		7.28	11.54	13.40
12 months	0.625	41.18	34.42	50.85	64.56
12 months	1.25		87.36	138.47	160.78

*Prices averaged for year

PBMs and MCOs move patients to their mail order component by typically decreasing the co-payment and allowing patients to obtain a 90 day supply of their drugs as opposed to the 30 day limit imposed on retail. When comparing the price difference for formulary versus non-formulary products in the mail order option it becomes very clear that the patient price difference is an important consideration. From Table IV below again it can be seen that patients will pay a significant differential between a 2d tier co-pay and cash price whether over the course of 90 days or one year.

Table IV

Cenestin Mail Order price difference from 2nd Tier Co-Pay
90 day supply*

		1999	2000	2001	2002
2nd Tier Co-Pays[9]		**17.96**	**21.29**	**26.01**	**31.18**
90 days	0.625	30.79	29.73	34.88	37.65
90 days	1.25	_____	42.97	56.79	61.72
12 months	0.625	123.18	118.94	139.53	150.59
12 months	1.25	_____	171.88	227.15	246.90

*Prices averaged for year

V. Duramed's Marketing Contained All Elements of a Standard Pharmaceutical Marketing Program, and These Elements Were Executed in a Standard Manner.

A. Cenestin marketing plan.

Duramed's original marketing plan for Cenestin was more than adequate. The addition of the Solvay marketing and sales team three months after launch provided all of the required marketing support and tools, as demonstrated by Duramed's 2000 marketing plan.

Dr. Kolassa's observation (Kolassa Report at 38) that a company needs to spend 100% of expected first year annual sales on promotion is not a standard formula. Wyeth's contracts with MCOs and PBMs severely damaged Duramed's ability to gain more sales and to generate more funds for marketing Cenestin.

B. Cenestin's marketing message was appropriate for each intended audience.

Appropriate market research was done to position Cenestin. The message of "plant based" was placed in initial direct-to-consumer pieces and was presented to physicians to prepare them for consumer requests. Other messages aimed at physicians stressed Cenestin's improved dissolution and consistent dosage delivery.

[9] Takeda Report average co-pays. McDonough 000065.

Dr. Kolassa inaccurately states that a change in message negatively affects sales. This is absolutely contrary to pharmaceutical marketing practice. Physicians and sales forces become bored and burned out if the message does not change. One of the things that energizes a sales force is when they can go to the physician with a new message. These new messages typically lead to increased sales. This is why most pharmaceutical companies create multiple POAs (Plan of Action) for their promotions throughout the year.

Dr. Kolassa's "cardinal rule in marketing", that "you never get a second chance to make a first impression" (Kolassa Report at 44) has little relevance in pharmaceutical marketing. Physicians as a rule do not change behaviors based on a first impression. As Dr. Kolassa has acknowledged, physicians typically adopt new habits only after a dialogue with representatives that extends over several visits.

C. Detailing.

While a sales force is an important marketing tool in the promotion of pharmaceutical products, I do not agree that "the number of feet you put on the street" (Kolassa II dep at 108) is the one most important issue for sales success. Dr. Kolassa finds fault with Cenestin detailing efforts, but after analyzing audit sources, it is my opinion that Duramed's detailing of Cenestin was appropriate in all respects.

i. Size

After adding Cardinal and Solvay sales forces together, Cenestin was being detailed by over 300 sales representatives. This places Cenestin as the fourth largest sales force by size in the broad HT market according to Dr. Kolassa's chart.[10]

ii. Experience

[10] Kolassa Report at 36.

Cenestin's sales force was sufficiently trained and scored equivalent to Wyeth in standard audit sources.

While the Cardinal sales group had less than 60% of sales reps that could be considered pharmaceutical veterans, Cardinal made up only 40% of the entire sales force. To put this issue of experience in perspective, the Cardinal representatives with less than one year of pharmaceutical experience only made up 17% of all sales reps, and all managers were veterans. Dr. Kolassa points to a preferred representative mix at 80/20 for "reasonably experienced reps" to "rookies" and the combined sales force approximated this criteria. (Kolassa Report at 40).

The Solvay sales force, which represented over 60% of the total sales force, was established and had relationships with the target population of doctors. Not only were they experienced pharmaceutical representatives but they had existing relationships with the "high prescribers" of ERT products and they had immediate credibility because they were already calling on the doctors in the target product category. The training Dr. Kolassa mentions for most major pharmaceutical companies includes product training for five or more products. The Cardinal sales representatives all had over 1 year of sales experience and were only charged with obtaining product knowledge for one product.

iii. Effectiveness

Standard pharmaceutical audits used to monitor sales efforts provide a perspective on the comparison between Cenestin and Premarin detailing effectiveness. The Scott-Levin data for the year 2000 shows that Cenestin provided more than 6% of details in the combined ERT/HRT market. In fact, compared to the ERT Wyeth product (Premarin alone) it can be seen in Table V that Cenestin had about one-third the conjugated estrogen details in 2000.

Table V

Details, Details Order and Detail Rating for ERT/HRT Market

	2000 PSA Calls(000)	2000 Mean Call Quality	2000 PSA Det (000)	Share %	2000 PSA Min (000)	Share %
WYETH	**1495**	**3.7**	352	29.4	1957	25.7
Estrogen			1	0.2	10	0.5
Premarin			159	45.2	850	43.4
Premphase			23	6.4	121	6.2
Prempro			170	48.2	976	49.9
SOLVAY PHARMACEUTICAL INC	**262**	**3.7**	50	4.2	263	3.5
Estratab			8	15.5	36	13.7
Cenestin			42	84.5	226	86.3
BARR LABS	**28**	**3.6**	27	2.2	188	2.5
Cenestin			27	100	188	100
SOLVAY/DURAMED CMKT	**2**	**4**	2	0.1	17	0.2
Cenestin			2	100	17	100

Source: Scott-Levin PSA, 6/02

The sales force focus for Cenestin promotion was more targeted than other competitive sales forces in the ERT marketplace. The marketing divisions of pharmaceutical manufacturers go to great lengths to make sure that representatives allocate their time across all products and the order of the presentation is a key goal in this process. The first product presented to physicians is designated as primary because it is the one physicians remember and it typically is the one given the most time. Manufacturers prepare POAs so that field management can direct activities and they usually tie bonus programs to these objectives. However, Duramed sales representatives had only one product to launch and their time in physician offices was not shared with other products. Cenestin was, in effect, presented to physicians first, second and third. Meanwhile, competitors promoted three or more products thereby diluting the sales message that was being given to the physician. A critical

advantage for the Duramed representative was that the product message left in a physician's mind when the sales representative left that office was always Cenestin. Table VI demonstrates the detailing activity and physician ratings for the presentations. The Cenestin product presentation ratings are equivalent to those of Wyeth, but Cenestin is more often given in the primary position.

Table VI

Details, Details Order and Detail Rating for ERT/HRT Market

	2000 Det Order 1st (000)	Share %	2000 Det Order 2nd (000)	Share %	2000 Det Order 3rd+(000)	Share %	2000 Det Order 1+2 (000)	Share %	2000 Mean Det. Rating*
Premarin	116	12.6	34	15.7	9	14.5	149	13.2	3.5
Prempro	103	11.3	55	25.7	11	17.2	158	14	3.4
Premphase	7	0.8	8	3.9	7	11.3	15	1.3	3.5
Cenestin	60	6.6	7	3.3	3	4.2	67	6	3.4

Source: Scott-Levin PSA, 6/02
*Based on physician rating of the overall value of the detail on a scale of 1 to 5 (1 is low & 5 is high)

When looking at detailing efforts it can be seen that, compared to Premarin, Cenestin details were longer, they were more often in the 1st or 2nd position and rated equal in terms of quality as those given by Wyeth.

The product positioning and messages that were provided by the sales force for Cenestin were appropriate and interesting.

D. Samples

Pharmaceutical companies provide samples for a variety of reasons: a) shelf pressure in the sample closet; b) as a reminder to physicians about the product; and c) as a vehicle to help physicians gain experience with the product. Physicians tend to use samples to: a) gain experience; b) provide

patients with a convenient no-cost starter (test) supply; c) to test for efficacy and side effects; d) to help assess the right dosage before prescribing; and e) to provide patients with a supply of product until they can conveniently get their prescription filled. The configuration of the sample package will be impacted by all of these things along with the market dynamics (e.g., duration of therapy, daily dosage, etc.) and there is no standard sample size.

Pharmaceuticals are either acute or maintenance products. Maintenance products are used over an extended period of time. The ERT and HRT categories are maintenance markets, where physicians need to titrate the dose. To appropriately assess dosage requirements, the patient needs to take the product for a sufficient time to test for effectiveness, side effects and to make sure the dose is correct. Anecdotal information in the ERT and HRT markets implies that physicians will typically give multiple 7 day sample packages to new patients to gain this information. As such, the 30 day sample package is actually the least costly option as the packaging cost would outweigh the cost of the tablets and not provide any benefit.[11]

I disagree that the use of a 30 day sample package was a "misapplied" use of samples and that it slowed prescription uptake (Kolassa Report at 44). The use of samples to gain physician familiarity in the ERT market would best be served by giving a full unit of therapy. Doctors want the patient to have sufficient experience with the product to know that it is working appropriately and does not produce unwanted effects. This will give the physician confidence that the patient can tolerate the treatment on a maintenance basis. Because market needs and product objectives change over time, the sample package needs to be considered as a part of the marketing plan and evaluated for how well it meets market needs over time with new packaging options considered as needed. This is why the sample package was changed to a smaller package after the initial launch.

[11] Typical packaging cost runs about a dollar for components and packing whereas the product ingredient costs for 100 tablets is normally less than $3 - $4.

If the 600,000 samples could have resulted in even half that number of patients (300,000), the investment would have been very well rewarded. The expected increase in sales did not materialize due to Wyeth's contracts.

VI. Wyeth's Rebate Contracts and Their Enforcement Were Not Standard in the Industry.

While I agree that it is standard practice in the pharmaceutical industry for drug manufacturers to enter into rebate contracts with MCOs and PBMs, several aspects of Wyeth's contracts take them outside the norm.

First, it is not "standard industry practice" to bundle branded products. In fact, most brand manufacturers would not leverage the value of one product to gain formulary placement for another product as a standard practice. Bundled contracts are more accepted in the generic industry because generic products are available from multiple sources and are freely and fully interchangeable.

Second, it is not "standard practice" in the industry for a drug manufacturer to have exclusive contracts with virtually every major PBM and MCO. Rebate contracts may provide increased rebates for preferred formulary position, but it is not common to have contracts that exclude a specific product with a large share of the biggest managed care companies as was the case with Wyeth's exclusive contracts for Premarin.

Third, it is not "standard practice" for a drug manufacturer to refuse to renegotiate a contract if an MCO or PBM wants to add another formulary agent, as by example, was the case with Wyeth's refusal to renegotiate with Express Scripts and Wyeth's refusal to allow Prescription Solutions to place Cenestin on formulary. These instances clearly refute Dr. Kolassa's assertion that customer demand would have gotten Cenestin on formulary with no problem. It is quite apparent that requests to have Cenestin added to the formulary were unavailing in the face of Wyeth's contracts.

Dr. Kolassa appears to think he has made a point in Wyeth's favor in observing that other

estrogens are on MCO and PBM formularies, apparently wishing the reader to infer that therefore Wyeth's contracts are not "exclusive." (Kolassa Report at 15). But the formulary inclusion of these other estrogens, which are not affected by Wyeth's "sole conjugated estrogen" clauses because they are not conjugated estrogens, is very powerful evidence that Wyeth's contracts were the cause of Cenestin's lower formulary acceptance.

VII. Wyeth's "Premarin Preemptive Plan" was not a standard marketing plan.

The fact that Wyeth prepared a plan to respond to the introduction of Cenestin is not the issue. No one would question Wyeth's right to plan for competition to its flagship brand. The problem is that the tactics Wyeth used were not "competition."

Wyeth 's contracting strategy insulated Wyeth from more vigorous price competition. Duramed documents show that rebated prices for Cenestin were in some instances far below rebated prices for Premarin. In the case of Aetna, Wyeth shared part of the Premarin Preemptive Plan, the "Cenestin Impact Model," to demonstrate to Aetna the rebates on all Wyeth products that would be lost if market share was moved to Cenestin. The "price" that Cenestin had to meet was rebates on Wyeth's entire product line, not just Premarin. That is not competing on price.

Wyeth was not competing on the merits of the drugs. While the Premarin Preemptive Plan does contain some elements having to do with the relative merits, those elements were not the material part of Cenestin contract negotiations. Instead, Wyeth's plan was to force managed care to choose between rebates on Wyeth's entire product line and Cenestin.

VIII. Summary and Conclusions

PBMs and MCOs have been able to prove their worth to manufacturers that provide millions of dollars to them in the form of rebates. There is a reason that pharmaceutical companies continue to reward these companies for formulary position and their ability to move market share through

mechanisms beyond just co-payment position. In today's pharmaceutical market, as in any market, the product must be available for it to be purchased and the fewer roadblocks put in front of the purchase the better. In the case of Cenestin, the managed care roadblocks came in the form of contracts that specifically targeted Cenestin.

Dr. Kolassa's "blame the victim" approach ignores pharmaceutical marketing realities. Many documents conclusively prove that it was Wyeth's contracts and not any shortcomings of either Cenestin or its manufacturer that led to Cenestin's lower than expected sales. Duramed launched Cenestin with an appropriate and capable marketing plan. My review of the documents shows that the factors that Dr. Kolassa deems to be the downfall of Cenestin were not the cause of its failure to achieve greater sales.

Date: September 30, 2004 Signature: 

PAUL O. SIMON, R.Ph.
12982 Duval Drive
Fishers, IN 46038

EXPERIENCE

Simon Consulting, LLC 2002 - Present

Provide consulting services to healthcare and related industries. Some examples include:

- Prepared forecasts, P&L analyses and defined licensing targets for a European company looking to enter the US institutional market.
- Consulted for a major Investment Banker on distribution channel economics.
- Provided Strategic Business Perspective and recommendations for a major Medical Device manufacturer.
- Participated in development of Strategic/Tactical Plans for brands being launched by a new company.
- Prepared a Business Plan for a company entering the Managed Care Services market.

Sigma-Tau Pharmaceuticals, Gaithersburg, MD 2001 – 2002

Privately held Italian company specializing in Metabolic Disorders and the Nephrology/Dialysis markets.

Vice President, Prescription Products

Provided leadership and direction to commercial operations and met corporate financial objectives within the Pharmaceutical Group. Responsible for commercial functions including; Customer Service, Distribution, Contracting, National Accounts and a Sales Force of 35 representatives and managers.

- Created a National Accounts sales force to build relationships and contracts with corporate customers.
- Mentored a new National Sales Manager and guided the development of a Sales Plan.
- Developed internal management structure and reorganized the marketing and sales functions.
- Created and implemented coordinated business plans for all commercial departments.
- Selected a new agency for promotion of our major brand.

TARO Pharmaceuticals, Hawthorne, NY 1998 - 2000

The leading manufacturer of ethical and OTC generic topical pharmaceuticals.

Vice President, North America Marketing

Provided marketing leadership and built the infrastructure to meet the needs of the organization. Developed and led all marketing/pricing functions and participated in senior management group.

- Launched six new products, on time and on budget while increasing revenue by 40%.
- Created and presented NTI product promotions (& contracts) to Chain and Wholesale customers.
- Developed a Long Range Planning model (8 years) to prioritize new product development and licensing opportunities.

MEDI-SPAN, Indianapolis, IN 1997 - 1998

The leading provider of knowledge bases and applications for use in automated clinical record systems.

Director, Market Planning

Led efforts to establish and achieve market objectives, strategies and tactics. Served as a member of the senior management team to prioritize all product/business development activities.

- Built marketing team and created marketing plans to introduce new technology products.
- Established a Vendor Advisory Panel which cemented relationships with major customers.
- Implemented new marketing planning processes with specific goals and timelines.
- Designed and implemented a project management system for convention activities.

EXHIBIT "A"

TEVA (formerly LEMMON) Company, Sellersville, PA 1993 - 1997

The second largest manufacturer of generic pharmaceuticals in the United States.

Director, Marketing and Managed Care

Directed the National Accounts sales force for managed care and government. Directed all marketing functions. Created and executed a marketing/sales plan and participated in establishing the strategic focus for the generic business. Developed and maintained relationships with major customers, negotiated and managed contracts, and participated in New Business Development efforts.

- Increased revenue from $93 million in 1992 to over $250 million in 1996.
- Prioritized new product development opportunities and developed templates for product launches based on margin opportunity.
- Increased government sales by more than 100% for each of the last two years and improved contribution from less than 1% to greater than 4% over four years.
- Created a promotional campaign that uniquely differentiated LEMMON from other generic manufacturers and positioned LEMMON as a leader without the need for documented claims.

BRISTOL-MYERS SQUIBB COMPANY, Evansville, IN 1987 - 1993

Leading manufacturer of pharmaceutical and nutritional products in the ethical and consumer package goods markets.

Manager, Worldwide Marketing Research (1989 - 1993)

Manager, Information Planning (1987 - 1988)

Directed the planning and coordination of primary marketing research for managed health care, women's healthcare pharmaceutical and consumer nutritional products worldwide, and an internal consumer database. Directed the activities of managers and analysts for business issues like; sales force sizing/alignment, incentive compensation, Decision Support Systems, and market research with a multimillion dollar budget.

- Designed, staffed, and implemented the marketing research function for the Consumer Brands and International divisions and conducted projects while departments were being staffed.
- Led new product development efforts with Gerber management that resulted in the launch of new products and improved partner relations.
- Investigated, negotiated and contracted for new sub-national prescription data source resulting in a $2 million annual savings.
- Led management task force that developed a five year Information/Technology Strategy, purchased Decision Support software and initiated two applications in EXPRESS.

HOFFMANN-LA ROCHE, INC., Nutley, NJ 1977 - 1987

Roche Labs is a leading manufacturer of ethical pharmaceutical products.

Manager - Marketing Research and Information Planning (1985 - 1987)

Senior Analyst - Marketing Research (1983 - 1984)

Sales Representative - Pharmaceutical and Clinical Labs (1977 - 1983)

Responsible for evaluation, planning, approval and prioritization of all Roche Labs data and computer/information projects. Served as the chairman of the Marketing Board Information Committee. Also, responsible for negotiating contracts, budgeting for all secondary data sources ($6 million) and managing the in-house research agency.

- Managed in-house marketing research agency that coordinated and fielded all primary marketing research activities and reduced supplier expenses by 40%.
- Spearheaded a four person task force that developed a Forecasting System resulting in an $8 million inventory reduction.
- Developed a perpetual Long Range Plan model used to plan and prioritize the new product portfolio.
- Turned a $12,000 clinical laboratory territory around to reach almost $1,000,000 in sales within 2 years.

SALES AWARDS

Roche awards for sales excellence:

- Roche Clinical Laboratories Legend (1982)
- Valium Sales Legend (1981)
- Presidents Achievement Award (1980)

EDUCATION/CERTIFICATION

Pharmacist
Retail and Hospital experience.

BS Ph Pharmacy, Ohio Northern University
Pharmacy licenses in Ohio, Pennsylvania and Florida

MATERIALS REVIEWED*

From Duramed Case:

Simon Report and Deposition in Duramed case.

Hill Deposition

Reference October 7, 2002 letter from Carolyn P. Courville to Peggy Balesteri listing documents reviewed in the Duramed case.

From J.B.D.L.:

Complaint

Kolassa Report and Deposition

McDonough Report

Schafermeyer Report

Gibson Report

Adamcik Deposition

Swartz Deposition

Carlton Report

Sarrel Report

WYE 116921-117040	AHP 424814-5
WYE 162066-9	AHP 345144-7
WYE 161111-3	AHP 345095-6
WYE 117994-118056	AHP 308486-9
WYE 132250-132311	AHP 339033-69
WYE 051510-6	DUR 006268-71
WYE 089414-8	VIK 000105-119
WYE 023598-9	http://www.medcohealth.com/comsumer/ehealth/druginfo
WYE 117064-5	
WYE 051568-80	

EXHIBIT "B"

* In addition to documents cited in the body of the Report.